K053426

FEB 7 2006

510(k) Summary - Elecsys Anti-Tg

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence

Submitter name, address, contact

Roche Diagnostics
9115 Hague Rd
Indianapolis IN 46250
(317) 521-3532

Contact person: Randy Johnson

Date prepared: December 7, 2005

Device name

Proprietary name: Roche Diagnostics Elecsys Anti-Tg

Common name: Anti-Thyroid Antibodies

Classification name: Thyroid Autoantibody Immunological Test System

Device description

The Elecsys Anti-Tg Assay is a two step sandwich immunoassay with streptavidin microparticles and electrochemiluminescence detection.

Results are determined using a calibration curve that is generated specifically on each instrument by a 2-point calibration and a master curve provided with the reagent bar code.

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510(k) Summary - Elecsys Anti-Tg, Continued

Intended use	Immunoassay for the in vitro quantitative determination of antibodies to thyroglobulin in human serum and plasma. The anti-Tg determination is used as an aid in the detection of autoimmune thyroid diseases. The electrochemiluminescence Immunoassay "ECLIA" is intended for use on the Roche Elecsys 1010/2010 and MODULAR ANALYTICS E170 (Elecsys module) immunoassay analyzers.
Predicate device	The Elecsys Anti-Tg is equivalent to other devices legally marketed in the United States. We claim equivalence to the Elecsys Anti-Tg (K020672).

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510(k) Summary - Elecsys Anti-Tg, Continued

Device comparison

The table below compares the Elecsys Anti-Tg (K020672) and the Elecsys Anti-Tg (modified device).

Topic	Elecsys Anti-Tg (K020672)	Elecsys Anti-Tg (Modified Device)
Intended use	Immunoassay for the in vitro quantitative determination of antibodies to thyroglobulin in human serum and plasma. The anti-Tg determination is used as an aid in the detection of autoimmune thyroid diseases. The electrochemiluminescence Immunoassay "ECLIA" is intended for use on the Roche Elecsys 1010/2010 and MODULAR ANALYTICS E170 (Elecsys module) immunoassay analyzers.	Same
Sample type	Human serum Human plasma treated with sodium heparin, or K2/K3-EDTA	Same
Assay Protocol	Competitive assay	Same
Detection Protocol	Electrochemiluminescence immunoassay	Same
Traceability	Calibrated against NIBSC 65/93 Standard	Same

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Device comparison, continued

The table below compares the Elecsys Anti-Tg (K020672) and the Elecsys Anti-Tg (modified device).

Topic	Elecsys Anti-Tg (K020672)	Elecsys Anti-Tg (Modified Device)
	CALIBRATORS	
Matrix	Human serum matrix	Same
	Origin of Anti-Tg antibodies: Cal1: Human Cal2: Human (Note: Human was incorrectly listed in the package insert upon submission. Cal2 was of sheep origin at the time of the submission.)	Origin of Anti-Tg antibodies: Cal1: Same Cal2: Sheep (Note: Correction of the error in the package insert from the K020672 filing)
Storage form	Calibrator: Liquid	Calibrator: Lyophilized
Target values	Cal 1: 40 IU/mL Cal 2: 3,250 IU/mL	Same
Stability	Unopened at 2 - 8°C: Up to the stated expiration date After opening: 8 weeks at 2 - 8°C On Elecsys 1010/2010 analyzer: Up to 5 hours at 20 - 25°C On E170: Use once only	Lyophilized: Up to the stated expiration date Reconstituted: 6 weeks at 2 - 8°C On Elecsys 1010/2010 at 20 - 25°C: Up to 5 hours On MODULAR ANALYTICS E170: Use only once
Filling volume	1.3 mL	1.5 mL

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Device comparison, continued

The table below compares the Elecsys Anti-Tg (K020672) and the Elecsys Anti-Tg (modified device).

Topic	Elecsys Anti-Tg (K020672)	Elecsys Anti-Tg (Modified Device)
	REAGENTS	
Stability	Unopened at 2 - 8°C: Up to the stated expiration date After opening: 12 weeks at 2 - 8°C On E170/Elecsys 2010: 6 weeks On Elecysys 1010: 6 weeks (stored alternately in the refrigerator and on the analyzer – ambient temperature 20 - 25°C; up to 20 hours opened in total)	Unopened at 2 - 8°C: Up to the stated expiration date After opening at 2 - 8°C: 6 weeks (Harmonized to calibrator stability claim) On MODULAR ANALYTICS E170: 6 weeks On Elecsys 2010: 6 weeks On Elecsys 1010: 6 weeks (stored alternately in the refrigerator and on the analyzer – ambient temperature 20 – 25°C; up to 20 hours opened in total)
Reagent 2 (R2)	Monoclonal anti-Tg antibodies (human) labeled with ruthenium complex 0.520 mg/L	Monoclonal anti-Tg antibodies (human) labeled with ruthenium complex 0.620 mg/L
	CONTROLS	
Stability	Unopened at 2 - 8°C: Up to the stated expiration date PC A-Tg1, PC A -Tg2, after opening: 8 weeks at 2 - 8°C On Elecsys 1010/2010 analyzers: up to 5 hour at 20 – 25°C On E170: use once only	Unopened at 2 - 8°C: Up to the stated expiration date PC A-TG1, PC A-TG2, after opening: 6 weeks at 2 - 8°C (Harmonized to calibrator stability claim) On Elecsys 1010/2010 at 20 - 25°C: Up to 5 hours On MODULAR ANALYTICS E170: Use only once

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 7 2006

Roche Diagnostics Corp.
c/o Randy J. Johnson MT (ASCP)
Regulatory Affairs Consultant
9115 Hague Rd.
Indianapolis, IN 46250

Re: k053426
Trade/Device Name: Roche Diagnostics Elecsys Anti-Tg
Regulation Number: 21 CFR 866.5870
Regulation Name: Thyroid autoantibody immunological test system
Regulatory Class: Class II
Product Code: JZO
Dated: December 7, 2005
Received: December 8, 2005

Dear Mr. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K053426

Device Name: Elecsys Anti-Tg

Indications For Use:

Immunoassay for the in vitro quantitative determination of antibodies to thyroglobulin in human serum and plasma. The anti-Tg determination is used as an aid in the detection of autoimmune thyroid diseases. The electrochemiluminescence Immunoassay "ECLIA" is intended for use on the Roche Elecsys 1010/2010 and MODULAR ANALYTICS E170 (Elecsys module) immunoassay analyzers.

Prescription Use **XXXX** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Maria Chan

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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